K071977

MAY 23 2008

510(k) Summary

Date Prepared [21 CFR 807.92(a)(1)]: Revised May 22, 2008

Submitter's Information [21 CFR 807.92(a)(1)]:

This 510(k) is being submitted by Joseph Azary on behalf Tarry Medical Products.

Contact:

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Sponsor / Manufacturer:

Tarry Medical Products (dba Tarry Manufacturing)
22 Shelter Rock Lane
Danbury, CT 06810
Tel: (203) 794-1438

FDA Establishment Registration# 1226711

Trade Name:

The device trade name is Tarry Medical Temperature Probes.

Device Common, Usual, or Classification Names:

Temperature Probes, Temperature Probes for Neonatal Incubators

Classification:

Class II, Product Code FMZ, Regulation 21 CFR 880.5400

Predicate Device [21 CFR 807.92(a)(3)]:

The following devices have been identified as predicate devices:

Ohmeda Inc – Ohmeda / Ohio Care Plus Incubators – K974349

Hill-Rom / Air Shields – Isolette Incubators – K001242 / K960980

Replacement Parts Industries – RPI Temperature Probes – K020219

Description of the Device [21 CFR 807.92(a)(4)]:

The Tarry Medical Temperature Probes are intended to be used as replacement parts as various neonatal incubators including:

- Drager / Air Shields / Hill-Rom Isolette Incubators
- Drager / Air Shields / Hill-Rom Incubators
- GE / Ohmeda / Ohio IC and GC Care Plus
- GE / Ohmeda Panda Baby Warmers
- GE / Ohmeda Infant Warmer Systems

This 510(k) includes the following probes:

T-100 (skin temperature probe)
T-3000 (skin temperature probe)
T-20970 (skin temperature probe)
T-20980 (air temperature probe)

The temperature probes are for use with incubators and warmers in a hospital setting. The probes are available in both disposable and reusable models. The probes were designed to meet OEM product specifications.

The temperature probes include thermistors and are used with disposable probe covers.

Intended Use [21 CFR 807.92(a)(5)]:

The Tarry Medical Temperature Probes are designed to be used as replacement temperature sensing probes for use with infant radiant warmers and infant incubators. The probes provide skin or air temperature feedback in order to maintain pre-selected temperature settings.

Technology Characteristics [21 CFR 807.92(a)(6)]:

The device is substantially equivalent to the predicate device based on material, technology, and performance.

Performance Data [21 CFR 807.92(b)(1)]:

The subject device has been subjected to biocompatibility, low level disinfection, accuracy, comparison, and electrical testing.

Conclusion [21 CFR 807.92(b)(3)]:

We believe the changes are minor and conclude that the subject devices are as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 23 2008

Tarry Medical Products, Incorporated
C/O Mr. Joseph M. Azary
Orchid Design Orthopedic Solutions
80 Shelton Technology Center
Shelton, Connecticut 06484

Re: K071977
Trade/Device Name: Tarry Medical Temperature Probes
Regulation Number: 21 CFR 880.5400
Regulation Name: Neonatal Incubator
Regulatory Class: II
Product Code: FMZ, FMT
Dated: April 30, 2008
Received: May 2, 2008

Dear Mr. Azary:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Tarry Temperature Probes (models T-100, T-3000, T-20970, T-20980)

Indications For Use: The Tarry Medical Temperature Probes are designed to be used as replacement temperature sensing probes for use with infant radiant warmers and infant incubators. The probes provide skin or air temperature feedback in order to maintain pre-selected temperature settings.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K971999